USSN: 09/910,628 Attorney Docket No: 3060.00021

## REMARKS

Claims 43-45 and 48 are currently pending in the application. Claims 43, 46 and 47 are in independent form.

Applicants wish to express their appreciation for the courtesies extended Applicant's representative, Amy E. Rinaldo, during a telephonic interview.

Claims 45 and 48 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Office Action states that the claims are vague because it is not clear how the pharmacological agents are related to the components of the apparatus of claim 43. The claims have been amended to more specifically recite the relationship between the pharmacological agents and the apparatus. Specifically, the claims have been amended to recite that the tissue is what is being screened and reconsideration of the rejection is respectfully requested.

Claims 43-45 stand rejected under 35 U.S.C. § 102(b) as being anticipated by the Charles, et al. patent. Reconsideration of the rejection under 35 U.S.C. § 102(b), as anticipated by the Charles, et al. patent, as applied to the claims is respectfully requested. Anticipation has always been held to require absolute identity in structure between the claimed structure and a structure disclosed in a single reference.

In <u>Hybritech Inc. v. Monoclonal Antibodies, Inc.</u>, 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986) it was stated: "For prior art to anticipate under §102 it has to meet every element of the claimed invention."

In <u>Richardson v. Suzuki Motor Co., Ltd.</u>, 868 F.2d 1226, 9 U.S.P.Q.2d 1913 (Fed. Cir. 1989) it was stated: "Every element of the claimed invention must be literally present, arranged as in the claim."

The Office Action states that the Charles, et al. patent discloses a surface plasmon resonance sensor and method of immunoassay using the SPR sensor. The disclosed method is used for assaying for an analyte, which is a member of a specific binding pair, using a solid surface having immobilized thereon a

USSN: 09/910,628 Attorney Docket No: 3060.00021

first reagent, which is a member of the specific binding pair. An analyte, which is a conjugate of a member of the specific binding pair, is located in a fluid. In the assay, the conjugate is either displaced by analyte binding or bound to the analyte when analyte is bound to the immobilized first reagent, and thus produces an alteration in SPR signal in response to the presence of analyte. However, when read more specifically, it is not an alteration in the signal, but instead the signal is either created or is eliminated as disclosed on page 6, lines 27-30, wherein it is disclosed that the test is qualitative or quantitative. Thus, the assay functions only to analyze the amount of signal.

In contradistinction, the presently pending independent claims claim a method of screening a pharmacological agent to determine if the agent is capable of altering biological tissue. The screen is used to determine if there is a binding interaction between a receptor and a nucleotide in the presence or absence of the pharmaceutical being assessed. Thus, while the immunoassay of the Charles, et al. patent can detect a binding partner of an analyte and a labeled conjugate of the analyte or a second binding partner of the analyte, it can only determine if the analyte is present in the system. What can be assumed from the detection is the amount of the analyte present in the sample. The presently claimed invention instead produces à specific interaction between a receptor and its nuclear response element, wherein the interaction is affected by confirmational changes in the receptor that can be induced by the pharmaceutical agents. Thus, the screen of the presently pending independent claims can be used to determine alterations in the signal, which alterations indicate an alteration of the binding interaction and thus the effect of a pharmaceutical reagent on this binding. In other words, the presently claimed screen recites a device that is capable of docketing how a pharmaceutical agent affects the ability of the receptor to bind to the response element. The immunoassay of the Charles, et al. patent only enables an individual to determine if the analyte is present in a sample. It does not enable a determination of the pharmaceutical effect of a pharmaceutical on the binding interaction between a receptor and its ability to bind to a response element. Since the Charles, et al. patent neither teaches nor discloses the screening of the presently pending independent claims, the claims are patentable

over the Charles, et al. patent and reconsideration of the rejection is respectfully requested.

The remaining dependent claims not specifically discussed herein are ultimately dependent upon the independent claims. References as applied against these dependent claims do not make up for the deficiencies of those references as discussed above. The prior art references do not disclose the characterizing features of the independent claims discussed above. Hence, it is respectfully submitted that all of the pending claims are patentable over the prior art.

In view of the present amendment and foregoing remarks, reconsideration of the rejections and advancement of the case to issue are respectfully requested.

The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account No. 11-1449.

Respectfully submitted,

KOHN & ASSOCIATES, RLLC

Amy E. Rinaldo, Reg. No. 45,791 30500 Northwestern Highway

Suite 410

Farmington Hills, Michigan 48334

(248) 539-5050

Dated: March 18, 2005

## CÉRTIFICATE OF MAILING BY "EXPRESS MAIL"

-Express Mail Mailing Label No.: EV 571 723 717 US Date of Deposit: March 18, 2005

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail-Post Office To Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to: Mail Stop: Non-Fee Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Marie M. Lally